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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/936,657	09/24/97	ECKSTEIN	F 228213

022249
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HM12/0816

EXAMINER

LEGUYADER, J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/16/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 11/27/98

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 44-57 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 44-57 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

BEST AVAILABLE COPY

Claims 41-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, and is repeated for the same reasons of record as set forth in the Official action mailed 11/27/98.

The claimed invention broadly reads on cleavage of target nucleic acid via ribozyme composed of modified nucleotides as claimed in any context from cells in culture to whole organisms. Applicants show only nuclease resistance in cells but not the ability of ribozymes with the modifications as recited in claims to bind and cleave targets in cells in any context. While the specification as filed teaches certain delivery regimes as argued in applicants 6/1/99 remarks, the specification as a whole fails to provide any specific or particular guidelines for engineering and successful delivery of ribozyme with the modifications contemplated such that such ribozymes would bind and cleave target in cells in any context. Note the known unpredictability in the art as taught by Branch cited in the previous Official action, where the successful targeting of ribozymes for delivery to cells and whole organisms remains with any specific guidelines due to finding accessible regions in the target nucleic acid in cells and delivery issues for such ribozyme to whole organisms, which breadth is embraced by the claims. To date only limited specific examples are known of ribozyme being delivered to whole organisms, and where such delivery results in cleavage. It is maintained that the instant specification teaches only nuclease resistance in cells in vitro and that no further guidance is provided for the successful delivered of such ribozymes to cells in any context to essentially any target, in view of the unpredictability known

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in the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to John L. LeGUYADER at telephone number (703) 308-0447. Please note that the examiner's compressed workweek day off is every Friday.

John L. LeGUYADER
August 12, 1999

JOHN L. LeGUYADER
PRIMARY EXAMINER
GROUP 1200
1680